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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,953	09/18/2001	Giorgio Minotti	LD0226(NP)	8528

7590

09/15/2003

Marla J. Mathias
Bristol-Myers Squibb Company
Patent Department
P.O. Box 4000
Princeton, NJ 08543-4000

EXAMINER

KHARE, DEVESH

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 09/15/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/954,953

Applicant(s)

MINOTTI ET AL.

Examiner

Devesh Khare

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-17 is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 13.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Applicant's Amendment and remarks filed on 4/30/03 on paper no. 14 is acknowledged.

35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bissery, U.S. Patent 5,908,835 of record.

Claims 1-14 are drawn to methods for the treating various cancers with taxol derivative and doxorubicin sequentially, simultaneously, in alternate order, wherein the dosage of doxorubicin is between 40-380 mg, the taxol derivative is between 50-300 mg, with variable administration intervals and modes of administration.

Bissery teaches the antitumor compositions comprising taxol derivatives in combination with an anthracycline antibiotic (see abstract). Bissery discloses taxol derivatives and doxorubicin combination as active agent for treating breast, ovarian and lung cancers (see col. 4, lines 46-51). Bissery also discloses in col. 4, lines 37-45, the modes of administration which are rendered obvious by the disclosure. Furthermore, under Example in col. 4, lines 56-67, the administration of 100 mg of Taxotere (taxol derivative) and 100 mg of etoposide (anthracycline antibiotic) for use in daily or weekly treatment is disclosed. Bissery differs from the applicant's invention that Bissery does not provide an explicit example of a taxol derivative in combination with the anthracycline derivative

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doxorubicin, however Bissery does provide motivation to use doxorubicin with a taxol derivative, and specifically 4-desacetyl-4-methylcarbonate taxol. Use of a known member of a class of materials in a process is not patentable if other members of the class were known to be useful for that purpose, even though results are better than expected.

Therefore, one of ordinary skill in the art would have found the applicants methods for the treating various cancers with taxol derivative and doxorubicin sequentially, simultaneously, in alternate order, wherein the dosage of doxorubicin is between 40-380 mg, the taxol derivative is between 50-300 mg, with variable administration intervals and modes of administration to have been obvious at the time the invention was made having the above reference before him because Bissery teaches the antitumor compositions comprising taxol derivatives in combination with an anthracycline antibiotic and the modes of administration.

2. Claims 15-17 are free of the prior art. Claims 15-17 are directed to a chemotherapeutic combination composition comprising an effective amount of 4-desacetyl-4-methylcarbonate taxol and doxorubicin, which is not taught or fairly suggested by the prior art of the record.

Rejection Maintained

Rejection of claims 1-14 under 35 U.S.C. 103(a) is maintained for the reasons of record.

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Response to Arguments

Applicant's arguments filed on April 30, 2003 traversing the rejection of claims 1-14 under 35 U.S.C 103(a) have been fully considered but they are not persuasive.

Applicants argue that the statement, "use of a known member of a class of materials in a process is not patentable if other members of the class were known to be useful for that purpose, even though the results are better than expected", is erroneous and contrary to the current state of the law. However, applicant's use of 4-desacetyl-4-methylcarbonate taxol is rendered obvious because the taxol, taxotere and their analogues and 4-desacetyl-4-methylcarbonate taxol have the same core structures (see applicant's figures 2 A, B and C). Applicant has not demonstrated any criticality or unexpected result, which stems from the use of 4-desacetyl-4-methylcarbonate taxol in a composition. It is noted that Bissery also discloses the relationship between the amount of a taxane derivative and the nature of the cancer to be treated (col. 4, lines 40-45, also see col. 1, lines 20-26).

Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is (703)605-

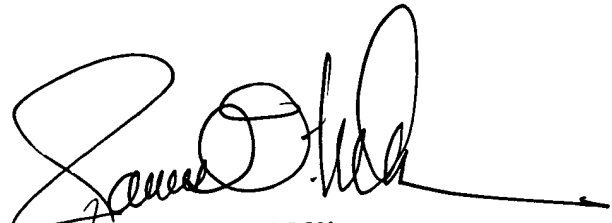
1199. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 703-308-4624. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,JD(3Y).
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September 10,2003



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600